

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re application of:** Kovacs *et al.*

**Application No.**

**Filed:** Herewith

**Confirmation No.** Not yet known

**For:** IDENTIFICATION OF A REGION OF THE  
MAJOR SURFACE GLYCOPROTEIN  
(MSG) GENE OF HUMAN  
PNEUMOCYSTIS CARINII

**Examiner:** Jeanine Anne Goldberg

**Art Unit:** 1634

**Attorney Reference No.** 4239-66050

MAIL STOP PATENT APPLICATION  
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**INFORMATION DISCLOSURE STATEMENT**  
**FOR CONTINUING APPLICATIONS**

Listed on the accompanying form PTO-1449 are several English-language and/or non-English-language documents. Applicants respectfully request that such documents be listed as references cited on the issued patent.

The present application relies upon U.S. Patent Application No. 09/762,724, which was filed February 9, 2001, for an earlier filing date under 35 U.S.C. § 120. Furthermore, documents listed on the accompanying form PTO-1449 were disclosed to or cited by the Patent Office in the earlier U.S. application.

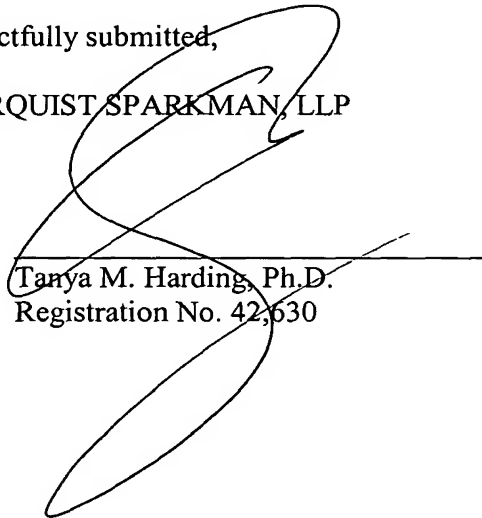
Copies of the documents listed on the accompanying form PTO-1449 that were cited by applicants in the earlier application need not be sent to the Patent Office pursuant to 37 C.F.R. § 1.98. However, applicants will furnish the Patent Office with such copies upon request. Copies of the four documents listed on the accompanying form PTO-1449 that were cited by the Patent Office in the earlier application are enclosed.

The filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, prior art or otherwise material to patentability as defined in Rule 56.

Respectfully submitted,

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			Tanabe <i>et al.</i> , "Glycoproteins Composed of Major Surface Immunodeterminants of <i>Pneumocystis carinii</i> ," <i>Infect. Immun.</i> , 57(5):1363-1368, May 1989
			Tang <i>et al.</i> , "Determination of copy number of rRNA genes in <i>Pneumocystis carinii</i> f. sp. <i>hominis</i> ," <i>J. Clin. Microbiol.</i> , 36(9):2491-2494, September 1998
			Theus <i>et al.</i> , "Cytokine responses to the native and recombinant forms of the major surface glycoprotein of <i>Pneumocystis carinii</i> ," <i>Clin. Exp. Immunol.</i> , 109:255-260, 1997
			Theus <i>et al.</i> , "Immunization with the major surface glycoprotein of <i>Pneumocystis carinii</i> elicits a protective response," <i>Vaccine</i> , 16:(11/12):1149-1157, 1998
			Wada <i>et al.</i> , "cDNA Sequence Diversity and Genomic Clusters of Major Surface Glycoprotein Genes of <i>Pneumocystis carinii</i> ," <i>J. Infect. Dis.</i> , 168:979-985, 1993
			Wakefield <i>et al.</i> , "Amplification of mitochondrial ribosomal RNA sequences from <i>Pneumocystis carinii</i> DNA of rat and human origin," <i>Mol. Biochem. Parasitol.</i> , 43:69-76, 1990
			Wakefield <i>et al.</i> , "Detection of <i>Pneumocystis carinii</i> with DNA amplification," <i>Lancet</i> , 336:451-453, August 25, 1990
			Wright <i>et al.</i> , "Cloning and characterization of a conserved region of human and Rhesus macaque <i>Pneumocystis carinii</i> <i>gpA</i> ," <i>Gene</i> 167(1-2):185-189, 1995
			Haidaris <i>et al.</i> , GenBank Accession No. AF043102, 6 June 1998.
			Edman <i>et al.</i> , GenBank Accession No. U53921, 24 December 1996
			Guadiz <i>et al.</i> , GenBank Accession No. AF035226, 2 January 1998
			Kovacs <i>et al.</i> , GenBank Accession No. U39660, 29 November 1995
			Wada <i>et al.</i> , GenBank Accession No. D31914, 22 September 1997
			Wada <i>et al.</i> , GenBank Accession No. D31920, 22 September 1997

EXAMINER:	DATE
*Examiner: Initial if considered, whether or not in conformance with MPEP 60; draw line through cite if not in conformance and not considered. Send copy.	

			Kovacs <i>et al.</i> , "Multiple Genes Encode the Major Surface Glycoprotein of <i>Pneumocystis carinii</i> ," <i>J. Biol. Chem.</i> , 268(8):6034-6040, March 15, 1993
			Leigh <i>et al.</i> , "Quantitative and qualitative comparison of DNA amplification by PCR with immunofluorescence staining for diagnosis of <i>Pneumocystis carinii</i> pneumonia," <i>J. Clin. Pathol.</i> , 46:140-144, 1993
			Line and Walzer, "Analysis of a surface antigen of <i>Pneumocystis carinii</i> ," <i>J. Protozool.</i> , 36(1):60S-61S, Jan-Feb 1989 (abstract only)
			Lipschik <i>et al.</i> , "Improved diagnosis of <i>Pneumocystis carinii</i> infection by polymerase chain reaction on induced sputum and blood," <i>Lancet</i> , 340:203-206, July 25, 1992
			Lopez <i>et al.</i> , "Europium(III) trisbipyridine cryptate label for time-resolved fluorescence detection of polymerase chain reaction products fixed on a solid support," <i>Clin. Chem.</i> , 39(2):196-201, February 1993 (abstract only)
			Mei <i>et al.</i> , "Characterization of Major Surface Glycoprotein Genes of Human <i>Pneumocystis carinii</i> and High-Level Expression of a Conserved Region," <i>Infect. Immun.</i> , 66(9):4268-4273, September 1998
			Moonens <i>et al.</i> , "Rapid Simple and Nested Polymerase Chain Reaction for the Diagnosis of <i>Pneumocystis carinii</i> pneumonia," <i>Scand. J. Infect. Dis.</i> , 27:358-362, 1995
			Nakamura <i>et al.</i> , "Structure of Major Surface Determinants and DNA Diagnosis of <i>Pneumocystis carinii</i> ," <i>J. Protozool.</i> , 36(1):58S-60S, Jan-Feb 1989
			Ognibene <i>et al.</i> , "The Diagnosis of <i>Pneumocystis carinii</i> Pneumonia in Patients with the Acquired Immunodeficiency Syndrome Using Subsegmental Bronchoalveolar Lavage," <i>Am. Rev. Respir. Dis.</i> , 129(6):929-932, June 1984
			Ortona <i>et al.</i> , "Non specific PCR products using rat-derived <i>Pneumocystis carinii</i> dihydrofolate reductase gene-specific primers in DNA amplification of human respiratory samples," <i>Mol. Cell. Probes</i> , 10:187-190, 1996
			Rys and Persing, "Preventing false positives: quantitative evaluation of three protocols for inactivation of polymerase chain reaction amplification products," <i>J. Clin. Microbiol.</i> , 31(9):2356-2360, September 1993 (abstract only)
			Santos <i>et al.</i> , "Use of the polymerase chain reaction in the diagnosis of leprosy," <i>J. Med. Microbiol.</i> , 46:170-172, 1997
			Schluger <i>et al.</i> , "Application of DNA Amplification to Pneumocystosis: Presence of Serum <i>Pneumocystis carinii</i> DNA During Human and Experimentally Induced <i>Pneumocystis carinii</i> Pneumonia," <i>J. Exp. Med.</i> , 176:1327-1333, November 1992
			Schluger and Rom, "The Polymerase Chain Reaction in the Diagnosis and Evaluation of Pulmonary Infections," <i>Am. J. Respir. Crit. Care Med.</i> , 152:11-16, 1995
		✖	Stringer <i>et al.</i> , "Genes Encoding Antigenic Surface Glycoproteins in <i>Pneumocystis</i> from Humans," <i>J. Euk. Microbiol.</i> 40(6):821-826, 1993

EXAMINER:

DATE

\*Examiner: Initial if considered, whether or not in conformance with MPEP 60; draw line through cite if not in conformance and not considered. Send copy.

OTHER DOCUMENTS			
			Baughman and Liming, "Diagnostic strategies in <i>Pneumocystis carinii</i> pneumonia," <i>Front. Biosci.</i> , 3:e1-12, January 1, 1998
			Bigby <i>et al.</i> , "The Usefulness of Induced Sputum in the Diagnosis of <i>Pneumocystis carinii</i> Pneumonia in Patients with the Acquired Immunodeficiency Syndrome," <i>Am. Rev. Respir. Dis.</i> , 133(4):515-518, April 1986
			Caliendo <i>et al.</i> , "Performance of a PCR assay for detection of <i>Pneumocystis carinii</i> from respiratory specimens," <i>J. Clin. Microbiol.</i> , 36(4):979-982, April 1998
			Chan <i>et al.</i> , "Quantification of polymerase chain reaction products in agarose gels with a fluorescent europium chelate as label and time-resolved fluorescence spectroscopy," <i>Anal. Chem.</i> , 65(2):158-163, January 15, 1993 (abstract only)
			Chary-Reddy and Graves, "Identification of Extrapulmonary <i>Pneumocystis carinii</i> in Immunocompromised Rats by PCR," <i>J. Clin. Microbiol.</i> , 34(7):1660-1665, July 1996
			Cimino <i>et al.</i> , "Post-PCR sterilization: a method to control carryover contamination for the polymerase chain reaction," <i>Nucleic Acids Res.</i> , 19(1):99-107, January 11, 1991 (abstract only)
			Dahlen <i>et al.</i> , "Detection of human immunodeficiency virus type 1 by using the polymerase chain reaction and a time-resolved fluorescence-based hybridization assay," <i>J. Clin. Microbiol.</i> , 29(4):798-804, April 1991 (abstract only)
			Dahlen <i>et al.</i> , "The use of europium (Eu <sup>3+</sup> ) labelled primers in PCR amplification of specific target DNA," <i>Mol. Cell. Probes</i> , 5(2):143-149, April 1991 (abstract only)
			De la Viuda <i>et al.</i> , "Use of AmpliWax to optimize amplicon sterilization by isopropyl alcohol," <i>J. Clin. Microbiol.</i> , 34(12):3115-3119, December 1996 (abstract only)
			Eskola <i>et al.</i> , "Detection of Philadelphia chromosome using PCR and europium-labeled DNA probes," <i>Clin. Biochem.</i> , 27(5):373-379, October 1994 (abstract only)
			Garbe and Stringer, "Molecular Characterization of Clustered Variants of Genes Encoding Major Surface Antigens of Human <i>Pneumocystis carinii</i> ," <i>Infect. Immun.</i> , 62(8):3092-3101, August 1994
			Helweg-Larsen <i>et al.</i> , "Diagnostic use of PCR for detection of <i>Pneumocystis carinii</i> in oral wash samples," <i>J. Clin. Microbiol.</i> , 36(7):2068-2072, July 1998
			Hierholzer <i>et al.</i> , "Detection of adenovirus in clinical specimens by polymerase chain reaction and liquid-phase hybridization quantitated by time-resolved fluorometry," <i>J. Clin. Microbiol.</i> , 31(7):1886-1891, July 1993 (abstract only)
			Isaacs <i>et al.</i> , "Post-PCR sterilization: development and application to an HIV-1 diagnostic assay," <i>Nucleic Acids Res.</i> , 19(1):109-116, January 11, 1991 (abstract only)
			Kovacs <i>et al.</i> , "Diagnosis of <i>Pneumocystis carinii</i> pneumonia: improved detection in sputum with use of monoclonal antibodies," <i>New England J. Med.</i> , 318(10):589-593, March 10, 1988
EXAMINER:			DATE
*Examiner: Initial if considered, whether or not in conformance with MPEP 60; draw line through cite if not in conformance and not considered. Send copy.			

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	<b>Atty Docket Number</b>	4239-66050
	<b>Application Number</b>	
	<b>Filing Date</b>	Filed herewith
	<b>First Named Inventor</b>	Kovacs
	<b>Art Unit</b>	1634
	<b>Examiner Name</b>	Jeanine Anne Goldberg

**U.S. PATENT DOCUMENTS**

Init.*		Number	Date	Name	Class	Sub	Filed
		4,683,195	July 28, 1987	Mullis <i>et al.</i>			
		5,164,490	Nov. 17, 1992	Santi <i>et al.</i>			
		5,442,050	Aug. 15, 1995	Fishman			
		5,501,947	March 26, 1996	Emery <i>et al.</i>			
		5,519,127	May 21, 1996	Shah <i>et al.</i>			
		5,593,836	Jan. 14, 1997	Niemiec <i>et al.</i>			
		5,595,874	Jan. 21, 1997	Hogan <i>et al.</i>			
		5,702,901	Dec. 30, 1997	Cummins <i>et al.</i>			
		5,776,680	July 7, 1998	Leibowitz <i>et al.</i>			

**FOREIGN PATENT DOCUMENTS**

		Number	Date	Country	Class	Sub	
		WO 91/19005	Dec. 12, 1991	WIPO			
		WO 94/09141	April 28, 1994	WIPO			

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